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Applicants Anuj Bellare, Wolfgang Fitz, Andreas H. Gomoll, Richard D. Scott and Thomas S. Thornhill

Application No.: 10/734,652 Group Art Unit: 1714

Filed: December 12, 2003 Examiner: Unknown

Confirmation No.: 8950

Title: NANOCOMPOSITE SURGICAL MATERIALS AND METHOD OF PRODUCING THEM

CERTIFICATE OF MAILING OR TRANSMISSION

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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

[ ] under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- [ ] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- [ ] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- [ ] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

[X] Enclosed herewith is form PTO-1449:

[X] Copies of the cited references are enclosed [AL3-AL4, AS7-AU8].

[X] Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

[X] Copies of the cited references [AA-AC2, AL-AQ2, AR-AR7] were entered in prior application, U.S. Application No. 09/541,374 (issued as U.S. Patent No. 6,689,823 B1), to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.

[ ] The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

[X] The "concise explanation" requirement (non-English references) for reference(s) [AM3-AN3 and AL4] under 37 CFR 1.98(a)(3) is satisfied by:

[ ] the explanation provided on the attached sheet.

[ ] the explanation provided in the Specification.

[ ] submission of the enclosed International Search Report.

[ ] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

[X] the enclosed English language abstract.

[ ] Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

- \_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

Examiner

Date

- [ ] A copy of each above-cited application, including the current claims, is enclosed.  
[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.  
[ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.  
[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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PTO-1449 REPRODUCED 	ATTORNEY DOCKET NO. 1407.1037-009	APPLICATION NO. 10/734,652
	FIRST NAMED INVENTOR Anuj Bellare	FILING DATE December 12, 2003
	EXAMINER Unknown	CONFIRMATION NO. 8950

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,500,658	02-19-1985	Fox
	AB	4,791,150	12-13-1988	Braden <i>et al.</i>
	AC	4,373,217	02-15-1983	Draenert
	AD	5,574,075	11-12-1996	Draenert
	AE	5,334,356	08-02-1994	Baldwin <i>et al.</i>
	AF	4,473,665	09-25-1984	Martini-Vvedensky <i>et al.</i>
	AG	4,588,583	05-13-1986	Pietsch <i>et al.</i>
	AH	5,328,262	07-12-1994	Lidgren <i>et al.</i>
	AI	4,735,625	04-05-1988	Davidson
	AJ	5,795,922	08-18-1998	Demian <i>et al.</i>
	AK	5,055,497	10-08-1991	Okada <i>et al.</i>
	AA2	6,020,396	08-01-2000	Jacobs
	AB2	6,013,591	01-11-2000	Ying <i>et al.</i>
	AC2	4,396,476	08-02-1983	Roemer <i>et al.</i>
	AD2	4,239,113	12-16-1980	Gross <i>et al.</i>
	AE2	4,490,497	12-25-1984	Evrard <i>et al.</i>
	AF2	4,617,327	10-14-1986	Podsun
	AG2	5,030,474	07-09-1991	Saita <i>et al.</i>
	AH2	5,797,873	08-25-1998	Franz <i>et al.</i>
	AI2	5,847,046	12-08-1998	Jiang <i>et al.</i>
	AJ2	6,080,801	06-27-2000	Draenert <i>et al.</i>
	AK2	6,197,410 B1	03-06-2001	Vallittu <i>et al.</i>
	AA3	6,203,844 B1	03-20-2001	Park
	AB3	3,156,666	11-10-1964	Pruett
	AC3	3,471,439	10-07-1969	Bixler, <i>et al.</i>
	AD3	4,124,562	11-07-1978	Yui, <i>et al.</i>

EXAMINER	DATE CONSIDERED

PTO-9449 REPRODUCED	ATTORNEY DOCKET NO. 1407.1037-009	APPLICATION NO. 10/734,652
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>	FIRST NAMED INVENTOR Anuj Bellare	FILING DATE December 12, 2003
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AR	Souheng Wu, E., "A Generalized Criterion for Rubber Toughening: The Critical Matrix Ligament Thickness," <i>J. Appl. Polymer Sci.</i> , 35: 549-561 (1988).
AS	Lewis, G., "Properties of Acrylic Bone Cement: State of the Art Review," <i>J. Biomed. Mater. Res.</i> , 38(2): 155-182 (1997).
AT	Molino, L. N., and Topoleski, L.D.T., "Effect of BaSO <sub>4</sub> on the Fatigue Crack Propagation Rate of PMMA Bone Cement," <i>J. Biomed. Mater. Res.</i> , 31: 131-137 (1996).
AU	Jacoby, M., "Photonic Crystals: Whole Lotta Holes Prepared by New Procedures, Materials With Arrays of Large Holes May Hasten Development of Optical-based Technologies," <i>C&amp;EN</i> , 11-23 38-43 (1998).
AV	Lewis, G., "Research Directions in Acrylic Bone Cement Studies," <i>BMES Bul.</i> , 20(1): 4-20 (1996).
AW	Wang, J. S., <i>et al.</i> , "Porosity of Bone Cement Reduced by Mixing and Collecting Under Vacuum," <i>Acta Orthop. Scand.</i> , 64(2): 143-146 (1993).
AX	Wixson, R., <i>et al.</i> , "Vacuum Mixing of Acrylic Bone Cement," <i>J. Arthroplasty</i> , 2(2): 141-149 (1987).
AY	Saha, S. and Pal, S., "Mechanical Properties of Bone Cement: A Review," <i>J. Biomed. Mater. Res.</i> , 18: 435-462 (1984).
AZ	Pascual, B., <i>et al.</i> , "New Aspects of the Effect of Size and Size Distribution on the Setting Parameters and Mechanical Properties of Acrylic Bone Cements," <i>Biomaterials</i> , 17(5): 509-516 (1996).
AR2	James, S. P., <i>et al.</i> , "Extensive Porosity at the Cement-Femoral Prosthesis Interface: A Preliminary Study," <i>J. Biomed. Mater. Res.</i> , 27: 71-78 (1993).
AS2	Fumich, R.M. and Gibbons, D. F., "Rate of Mixing and the Strength of Methylmethacrylate Bone Cements," <i>Orthopaedic Rev.</i> , 8(9): 41-44 (1979).
AT2	Bishop, N.E., <i>et al.</i> , "Porosity Reduction in Bone Cement at the Cement-Stem Interface," <i>J. Bone Surg.</i> , 78-B(3): 359-356 (1996).
AU2	Topoleski, L.D., <i>et al.</i> , "Microstructural Pathway of Fracture in Poly(methyl methacrylate) Bone Cement," <i>Biomaterials</i> , 14(15):1165-1172 (1993).

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AV2	Mapleston, P., "Broad Use Spectrum Seen for Microcellular Injection technique," <i>Modern Plastics</i> December(1998). page 31
AW2	Schreurs,B.W., <i>et al</i> "Effects of Preparation Techniques on the Porosity of Acrylic Cements," <i>Acta Orthop Scand</i> 59(4):403-409 (1988).
AX2	Müeller-Wille, <i>et al.</i> , "Integrated System for Preparation of Bone Cement and Effects on Cement Quality and Environment," <i>J. Biomed. Mat. Res.</i> , 38(2):135-42 (1997) Summer.
AY2	Knoell, A., <i>et al.</i> , abstract, Ei Compendex®, "Graphite Fiber Reinforced Bone Cement," <i>Ann. Biomed. Eng.</i> , 3(2): 225-229 (1975).
AZ2	Kindt-Larsen, Ture, <i>et al.</i> "Innovations in Acrylic Bone Cement and Application Equipment," <i>J. App. Biomater.</i> , 6:75-83 (1995).
AR3	Fritsch, E. W., "Static and Fatigue Properties of Two New Low-Viscosity PMMA Bone Cements Improved by Vacuum Mixing," <i>J. Biomed. Mat. Res.</i> , 31:451-456 (1996).
AS3	Connelly, T. J., <i>et al.</i> , "The Role of Porosity in the Shrinkage of Acrylic Bone Cement," Trans 13 <sup>th</sup> Mtg. Soc. Biomat, June 2-6, New York, NY 1987.
AT3	Haas, S. S., <i>et al.</i> , "A Characterization of Polymethylmethacrylate Bone Cement," <i>J. Bone Joint Surg.</i> , 57-A:380-391 (1975).
AU3	Sabokbar, A., <i>et al.</i> , abstract Medline®, "Radio-Opaque Agents in Bone Cement Increase Bone Resorption," <i>J. Bone Joint Surg. Br.</i> , 79(1):129-134 (1997).
AV3	Lazarus, M.D., <i>et al.</i> , abstract Medline®, "Comparison of the Inflammatory Response to Particulate Polymethylmethacrylate Debris With and Without Barium Sulfate," <i>J. Orthop Res.</i> , U.S., 12(4):532-541 (1994).
AW3	Topoleski, L.D., <i>et al.</i> , abstract Medline®, "A Fractographic Analysis of <i>in vivo</i> Poly(methyl Methacrylate) Bone Cement Failure Mechanisms," <i>J. Biomed Mater Res.</i> , 24(2):135-154 (1990).
AX3	Nakahara, M., abstract Medline®, "An Objective Examination for Painful Hip After Total Hip Arthroplasty," <i>Acta Orthop. Scand.</i> 53(4):591-600 (1982).

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AY3	Rudigier, J., <i>et al.</i> , abstract Medline®, "Release and Diffusion of Methylmethacrylic Monomers After the Implantation of Self Curing Bone Cements," <i>Unfallchirurgie</i> , 7(3):132-137 (1981).
AZ3	Beaumont, P.W., abstract Medline®, "Fracture Processes in Acrylic Bone Cement Containing Barium Sulphate Dispersions," <i>J. Biomed Eng.</i> , 1(3): 147-152 (1979).
AR4	Rudigier, J., <i>et al.</i> , abstract Medline®, "Biological Effect of Bariumsulfate as Contrast Material in Bone Cement," 86(3):279-290 (1976).
AS4	Friis, E.A., <i>et al.</i> , abstract Ei Compendex®, "Fracture Toughness of Surface-Treated Carbon Fiber Reinforced Composite Bone Cement," <i>Transactions of the Annual Meeting of the Society For Biomaterials</i> , St. Louis Park, MN, USA, Pg. 913. (1996)
AT4	Lerouge, S., <i>et al.</i> , abstract Medline®, "Characterization of <i>in vivo</i> Wear Debris From Ceramic-Ceramic Total Hip Arthroplasties," <i>J. Biomed. Mater Res.</i> , 32(4):627-633 (1996).
AU4	Yoshida, K., and Greener, E.H., abstract Medline®, "Effects of Coupling Agents on Mechanical Properties of Metal Oxide-Polymethacrylate Composites," <i>J. Dent.</i> , 22(1):57-62 (1994).
AV4	Hopf, C., <i>et al.</i> , abstract Medline®, "Comparative Studies on the Radioactivity of Bone Cements Containing X-Ray Contrast Media and of the Contrast Media," <i>Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr</i> , 152(5):601-200 (1990).
AW4	Streicher, R.M., <i>et al.</i> , abstract Medline®, "New Surface Modification for Ti-6Al-7Nb Alloy: Oxygen Diffusion Hardening (ODH)," <i>Biomaterials</i> , 12(2):125-129 (1991).
AX4	Hopf, W., <i>et al.</i> , abstract Medline®, "About Radioactivity in Some PMMA Bone Cements," <i>Acta Orthop. Belg.</i> , 56(2):443-444 (1990).
AY4	Gross, U., and Strunz, V., abstract Medline®, "The Interface of Various Glasses and Glass Ceramics With a Bony Implantation Bed," <i>J. Biomed. Mater Res.</i> , 19(3):251-271 (1985).
AZ4	Bhambri, S.K., and Gilbertson, L.N., abstract Medline®, "Micromechanisms of Fatigue Crack Initiation and Propagation in Bone Cements," <i>J. Biomed. Mater Res.</i> , 29(2):233-237 (1995).
ARS	Owen, A.B., and Beaumont, P.W., abstract Medline®, "Fracture Behaviour of Commercial Surgical Acrylic Bone Cements," <i>J. Biomed Eng.</i> , 1(4):277-280 (1979).

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AS5	Freitag, T.A., and Cannon, S.L., abstract Medline®, "Fracture Characteristics of Acrylic Bone Cements, I. Fracture Toughness," <i>J. Biomed. Mater Res.</i> , 10(5):805-828 (1976).
AT5	Holland, B.T., et al., "Synthesis of Macroporous Minerals With Highly Ordered Three-dimensional Arrays of Spheroidal Voids," <i>Science</i> , 81:538-540.
AU5	Gilbert, J.L., and Ney, D.E., abstract, RAPRA Rubber & Plastics, "Self-Reinforced Composite PMMA: Static and Fatigue Properties," <i>Biomaterials</i> , 16(14):1043-1055 (1995).
AV5	Pourdeyhimi, B., et al., abstract, Ei Compendex®, "Comparison of Mechanical Properties of Discontinuous Kevlar 29 Fibre Reinforced Bone and Dental Cements," <i>J. Mat. Sci.</i> , 21(12):4468-4474 (1986).
AW5	James, S.P., et al., "A Fractographic Investigation of PMMA Bone Cement Focusing on the Relationship Between Porosity Reduction and Increased Fatigue Life," <i>J. Biomed. Mater. Res.</i> , 26:651-652 (1992).
AX5	Jasty, M., et al., "The Initiation of Failure in Cemented Femoral Components of Hip Arthroplasties," <i>J. Bone Joint Surg.</i> , 73(B):551 (1991).
AY5	Pourdeyhimi, B., et al., "Elastic and Ultimate Properties of Acrylic Bone Cement Reinforced with Ultra-High-Molecular-Weight Polyethylene," <i>J. Biomed. Materials Res.</i> , 23(1): 63-80 (1989).
AZ5	Burke, D.W., et al., "Centrifugation as a Method of Improving Tensile and Fatigue Properties of Acrylic Bone Cement," <i>J. Bone Joint Surg.</i> , 66(A):1265-1273 (1984).
AR6	Davies, J.P., et al., "The Effect of Centrifuging Bone Cement," <i>J. Bone Joint Surg.</i> , 71(B):39-42 (1989).
AS6	Davies, J.P., et al., "Comparison of the Mechanical Properties of Simplex P, Zimmer Regular, and LVC Bone Cements," <i>J. Biomed. Mater. Res.</i> , 21:719-730 (1987).
AT6	Topoleski, L.D., et al., "The Effects of Centrifugation and Titanium Fiber Reinforcement on Fatigue Failure Mechanisms in Poly(methyl methacrylate) Bone Cement," <i>J. Biomed. Mater. Res.</i> , 29:299-307 (1995).
AU6	Lewis, G, et al., "Effect of Mixing Method on Selected Properties of Acrylic Bone Cement," <i>J. Biomed. Mater. Res.</i> , 38:221-227 (1997).

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AV6	Trieu, H.H., et al., "A Comparative Study of Bone Cement Preparation Using a New Centrifugation Mixing Technique," <i>The 20<sup>th</sup> Annual Meeting of the Society for Biomaterials</i> , April 5-9, Boston, Massachusetts (1994).
AW6	Trehanne, R.W., and Brown, N., abstract Medline®, "Factors Influencing the Creep Behavior of Poly(Methyl Methacrylate) Cements," <i>J. Biomed Mater. Res.</i> , 9(4): 81-88 (1975).
AX6	Imhof, A., and Pine, D.J., "Ordered Macroporous Materials by Emulsion Templating," <i>Nature</i> , 389(30): 948-951 (1997).
AY6	Pedley, R.B., et al., abstract Medline®, "Identification of Acrylic Cement Particles in Tissues," <i>Ann. Biomed. Eng.</i> 7(3-4):319-328 (1979).
AZ6	Dernian, et al., "Regulatory Perspective on Characterization and Testing of Orthopedic Bone Cement," <i>Biomaterials</i> , 19:1607-1618 (1998).
AR7	Wu, S., "A Generalized Criterion for Rubber Toughening: The Critical Matrix Ligament Thickness ,," <i>J. Appl. Polym. Sci.</i> , 35:549-561 (1988).
AS7	Charnley, J., "Anchorage Of The Femoral Head Prosthesis To The Shaft of The Femur," <i>The J. of Bone and Joint Surgery</i> , 42-B:28-30 (1960)
AT7	Friis, E. A., et al., "Fracture Toughness Of Vacuum Mixed PMMA Bone Cement," <i>Transactions, Nineteenth Annual Meeting of the Society For Biomaterials, April 28 - May 2, 1993</i> , 16:301 (1993)
AU7	Skinner, H. B., et al., "Density Gradients In Bone Cement After Centrifugation," <i>Transactions, 31st Annual Meeting Orthopaedic Research Society, Las Vegas, Nevada, January 21-24, 1985</i> , 10:243 (1985)
AV7	Gharpuray, V. M., et al., "Cracks Emanating From Circular Voids or Elastic Inclusions in PMMA Near a Bone-Implant Interface," <i>Transactions Of The ASME, J. Of Biomech. Engineer.</i> , 112(1):22-28 (1990)
AW7	Kurtz, S. M., et al., "Advances in the Processing, Sterilization, and crosslinking of ultra-high molecular weight polyethylene for total joint arthroplasty," <i>Biomaterials</i> , 20(18):1659-1688 (1999)
AX7	Vila, M. M., et al., "Effect of Porosity and Environment on the Mechanical Behavior of Acrylic Bone Cement Modified With Acrylonitrile-Butadiene-Styrene Particles: I. Fracture Toughness," <i>J. Of Biomed. Materials Research</i> , 48:121-127 (1999)

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